USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Required Report - Public distribution

Date: 7/15/2008

GAIN Report Number: UP8011

Ukraine

Biotechnology

Agricultural Biotechnology Report

2008

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Report Highlights:

Currently, Ukraine has no functioning biotech approval or regulatory system despite adoption of the new biotech law on May 31, 2007. As GOU works on creating and implementing a new system that will approve and regulate products of agricultural biotechnology, Ukraine will continue to operate without a functioning system to regulate, test, and approve biotech products.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Kiev [UP1]
[UP]

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Executive Summary

The current regulatory process for approval of biotech crops in Ukraine is very cumbersome and is based on mandatory registration procedures designed for conventional plant varieties. A biotech plant variety is required to go through a more rigid and lengthy registration process than a variety using conventional plant breeding. However, no biotech variety has ever been approved or registered for cultivation in Ukraine.

Some progress has been! The Ukrainian parliament (Rada) voted on and adopted the "Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms" on May 31, 2007. However, this law is a broad "umbrella" law that lacks implementing regulations. Recently, Ukraine has made some progress on drafting implementing regulations but continue to face obstacles especially with the Ministry of Environment. Below are remaining obstacles that need to be resolved:

1) Ministry of Environment: The anti GMO groups have successfully lobbied and influenced the Ministry of Environment. The ministry is now viewed as the single biggest obstacle to establishing a functioning biotech framework.

2) Labeling/Testing: Ukraine seems committed to implementing mandatory labeling. The State Standards Committee and Ministry of Health both have plans for widespread testing for the presence of GM. This is not compatible with Ukraine's WTO obligations and is counterproductive to Ukraine's stated goal of encouraging the use of biotechnology in agriculture. This appears to be driven by Ministry intentions to use testing as revenue generating while placating activist opposition.

3) The Biotech Issue Continues to Face Media Criticism: There continues to be a barrage of negative press and widespread misunderstanding about biotechnology and the safety of these products. Very rarely does the media present a balanced news story on biotechnology so rumors and innuendo are widespread. To change these perceptions, the government must respond to the barrage of negative stories and also educate consumers, scientists and policy makers to the realities of biotechnology.

4) No Registration Process: There is no registration process for importing, field testing, or growing biotech crop varieties. However, many in the industry believe that many of these obstacles could be some of the easiest to overcome.

Section II. Biotechnology, Trade and Production

Production

Ukraine has not approved a single biotech variety for commercial production despite having received five applications during 1997-1999. Therefore, authorities claim that Ukraine's agriculture remains GMO-free. A weak regulatory system and lack of field surveillance programs, however, leave doubt to Ukraine's GMO free status. In fact, it is estimated that half of Ukraine's soybean production, or 375,000 tons, are Round-up Ready Soybeans. Other plantings of biotech crops are also suspected (i.e.: corn, sugar beats).

Ukrainian researchers in cooperation with a Russian scientist reportedly developed potatoes resistant to the X-virus in 1990. This was the first transgenic plant in the Former Soviet Union (FSU). Since then, research in this area has continued in the Institute of Cell Biology and Genetic Engineering (ICBGE) of the National Academy of Sciences of Ukraine, and Institutes of the Ukrainian Academy of Agricultural Sciences. According to available

information, Ukrainian researchers developed transgenic sugar beets, potatoes, tobacco, rapeseeds, cabbage, alfalfa, soybeans, peas, flax, barley, buckwheat, and African millet. Most of these plants were developed for scientific purposes using non-patented technologies and utilized germplasm of the local varieties to gain insect resistance or herbicide tolerance.

Reportedly, scientists from the ICBGE developed transgenic soybeans, flax and African millet with *dinitranilin* resistant features (*Treflan* and other herbicides produced by DowAgro Sciences Co.). However, the technology has not yet been patented. All plants remain in the laboratory environment and have gone through the seed propagation stage. Ukrainian scientists also developed technology for plant recombinant proteins used in pharmacology -- α-interferon and somatropine (human growth hormone). However, this technology has not yet been commercialized.

Trade

Imports of food and agricultural products to Ukraine totaled $4.1 billion in 2007, up from $3.2 billion in 2006. The United States captured 5% ($228) of the import market share in 2007. Major U.S. food and agricultural products exported to Ukraine were poultry meat, fish, tobacco, planting seeds, soybean meal, pet food, proteins derived from soybeans and tree nuts. According to FAS-Kyiv estimates, the value of U.S. soybean meal, soy proteins and isolates, corn products, planting seeds and other products that faced, or could have encountered trade restrictions, because of unclear biotechnology regulations ranged from $1.1 million (2003) to $20 million (2007). As long as Ukraine has no functioning system for biotech products, issues of market access for products of agricultural biotechnology are expected to become more critical as Ukraine continues to increase its oilseed processing capacity.

Below is a summary of Ukraine's import data for major products that might contain biotech corn or soybean events: Corn Flour (HS 110220); Corn Meal or Groat (HS 110313); Worked Corn (HS 110423); Soybeans (HS 120100); Soy Sauce (HS 210310); Protein Concentrates (HS 210610); Corn Gluten (HS 230310); Soybean Meal (HS 230400); Protein Isolates (HS 350400). Please note that prepared food products and feeds were not targeted in this research.

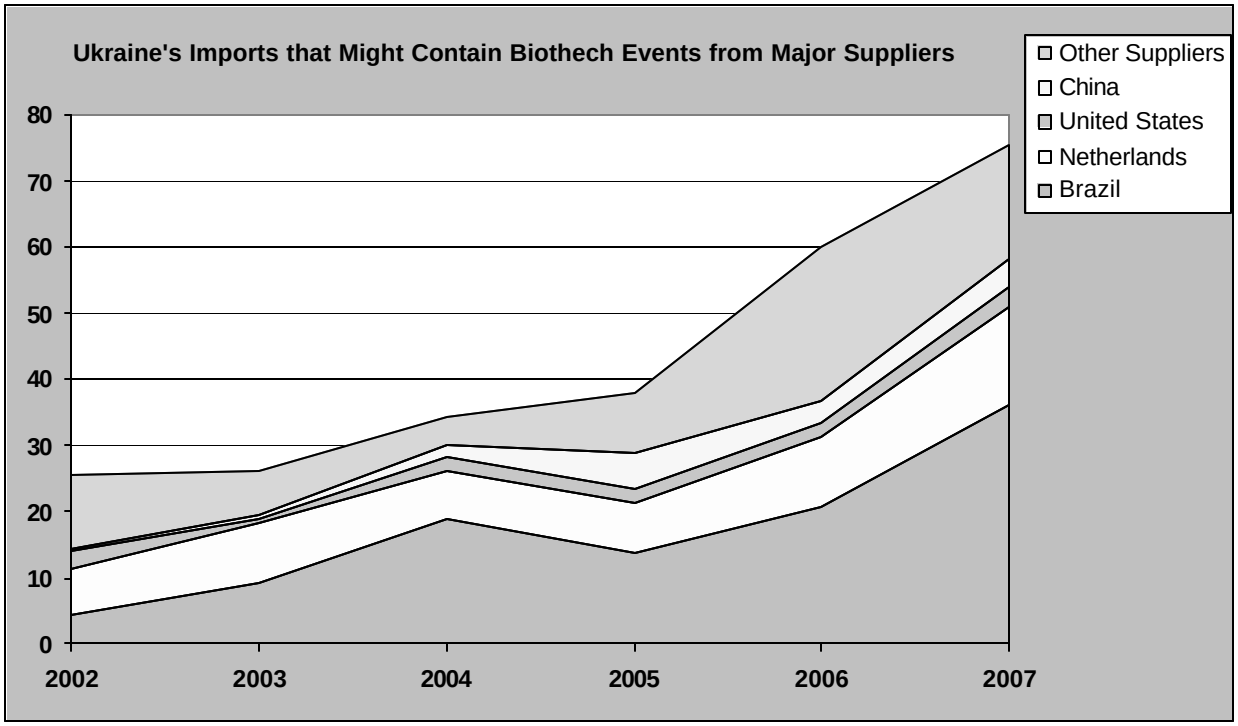
Ukraine imported products valued at $77 million in 2007 that could contain GMOs, up from $62 million the year before.

Imports of Products that Could be Affected by Ukraine's Biotech Regulations

	2005		2006		2007	
	Value $ million	Share %	Value $ million	Share %	Value $ million	Share %
Corn Flour (HS 110220);	0.382	1%	0.107	0%	0.072	0%
Corn Meal or Groat (HS 110313);	0.033	0%	0.008	0%	0.068	0%
Worked Corn (HS 110423);	0.001	0%	0	0%	0	0%
Soybeans (HS 120100);	0.05	0%	0.727	1%	0.489	1%
Soy Sauce (HS 210310);	0.325	1%	0.433	1%	0.714	1%
Protein Concentrates (HS 210610);	3.346	9%	6.188	10%	7.138	9%
Corn Gluten (HS 230310);	0.118	0%	0.069	0%	0.051	0%
Soybean Meal (HS 230400);	25.476	66%	47.299	77%	59.465	77%
Protein Isolates (HS 350400)	9.061	23%	6.571	11%	8.778	11%
Total Value, $ million	**38.792**	**100%**	**61.402**	**100%**	**76.775**	**100%**

Source: State Statistics Committee of Ukraine

The United States is the fourth largest supplier of these products after Brazil, China and Netherlands (please refer to the graph below).



Source: Prepared by FAS-Kyiv based on Ukraine's official trade data for the following HS Codes: 110423; 120100; 210310; 210610; 230310; 230400; 350400.

The following table illustrates U.S. exports of food and agricultural commodities that are affected, or might be affected, if Ukraine fails to complete implementation of an approval and regulatory system for products of biotechnology.

Imports of U.S. Products that Could be Affected by the Lack of Biotech Regulations in Ukraine (CIF, $ million)

HS Code	Description	2003		2004		2005		2006		2007	
		Value $ mln	Share %	Value $ mln	Share %	Value $ mln	Share %	Value $ mln	Share %	Value $ mln	Share %
230400	SOYBEAN MEAL	0.24	21%	1.18	51%	0.17	7%	0.1144	5%	0.893	31%
350400	PEPTONE, PROTEIN ISOLATES	0.43	37%	1.04	45%	1.75	71%	1.39326	58%	1.469	51%
210610	PROTEIN CONCENTRATE	0.01	1%	0.05	2%	0.48	19%	0.40451	17%	0.324	11%
120100	SOYBEANS	0.06	6%	0.04	2%	0.03	1%	0.3656	15%	0.068	2%
210310	SOY SAUCE	0.01	1%	0.01	1%	0.02	1%	0.10876	5%	0.144	5%
230310	CORN GLUTEN	0.4	35%	0	0%	0	0%	0	0%	0	0%
110423	WORKED CORN	0	0%	0	0%	0	0%	0	0%	0	0%

Total	1.15	100%	2.34	100%	2.46	100%	2.39	100%	2.898	100%

Source: State Statistics Committee of Ukraine

The future impact of Ukraine's biotech policy on agricultural trade, however, is not only guided by the information provided in the table above. One new crushing plant capable of crushing soybeans is scheduled to begin operations in the Port of Illichivsk (near Odesa) in MY 2008/2009. Some small crushers are already interested in importing soybeans from the United States, because the current Ukrainian crop is not large enough to satisfy both Ukrainian exporters and crushers.

Section III. Biotechnology Policy and Legislation

Legislation

On May 31, 2007, the Ukrainian parliament (Rada) voted on and adopted the "Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms". The law was signed by the President on June 11, 2007 and published on June 21, 2007. Ukraine committed to establishing a functioning approval and regulatory framework for biotech products prior to WTO accession, which occurred on May 16, 2008. Although, Ukraine has made some progress drafting implementing regulations, much more work must be accomplished before a functioning system is operational.

There are some in the government of Ukraine that see the benefits biotech products can deliver to Ukrainian agriculture. These officials and scientists have been instrumental in persuading key policy officials into supporting and approving legislation for agricultural biotechnology. However, there continues to be many dissenters and biotechnology remains a very sensitive issue in Ukraine.

Ukraine continues to draft implementing regulations. The task is difficult because there are 5 government institutions (State Standards Committee, Ministry of Education and Science, Ministry of Agriculture, Ministry of Heath and Ministry of Environment) that are involved and each has their own objectives. Below is the status of pending draft implementing regulations by organization:

Ministry of Education and Science: Draft implementing regulations are ready for submission to the Cabinet of Ministers for review and approval;

Ministry of Agriculture:

a). Draft Resolution "On approving the procedure for state testing and state registration of genetically modified crops" (State Service of protection of plant varieties rights) – is approved by the Ministry of Justice and ready to be submitted to the Cabinet of Ministers of Ukraine;

b). Draft Resolution "On approving the procedure for state testing and state registration of sources of feeds, feed additives, premixes and veterinary preparations, produced on the basis of GMOs" (responsibility with the Veterinary Service) was sent for comments to interested ministries;

Ministry of Heath: submitted to the Cabinet of Ministers;

Ministry of Environment: submission of the drafts to the Cabinet of Ministers was postponed until September 1, 2008. Currently, the drafts are at the Ministry of Justice.

National Standards

The State Committee for Technical Regulation and Consumer Policy (Derzhspozhyvstandard) approved the International Standards Methods of Analysis for the Detection of Genetically Modified Organisms and Derived Products which became effective in Ukraine as national standards on May 1, 2008.

The Respective Order No 62 was signed by the Head of Derzhspozhyvstandard on February 19, 2008.

According to the Order the following standards will become effective from May 1, 2008:
- DSTU CEN/TS 15568:2008 (Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Sampling strategies);
- DSTU ISO 21 organisms and derived products - qualitative nucleic acid based);
- DSTU ISO 21570:2008 Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods);
- DSTU ISO 24276:2008 (Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions);
- DSTU ISO 21571:2008 (Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Nucleic acid extraction).569:2008 (Foodstuffs - Methods of analysis for the detection of genetically modified.

Field Trails of Biotech Varieties in Ukraine

In 1998, GOU authorized field trials for biotech crops along with an environmental and food safety assessment. Insect resistant (Bt) potatoes and herbicide tolerant sugar beets, corn and rapeseed underwent full-scale field trials in 1998-2000. None have received final approval, however, due to the unwillingness of decision-making authority to take full responsibility for the approval of these products, especially since Ukraine has no established system for approving biotech varieties.

Field Trials of Genetically Modified Crops in Ukraine

Trait	*Crop*	Number of varieties	Applicant	Year of application	Status
BT (insect resistance)	Potatoes	3	Monsanto	1997	Pending
Glyphosinate tolerance (Liberty Link)	Sugar beets	1	Syngenta/ Monsanto	1998	Pending
BT (insect resistance)	Corn	1	Syngenta	1998	Pending
Glyphosinate tolerance (Liberty Link)	Rapeseed	1	Bayer	1998	N/A
Glyphosate tolerance (Roundup)	Corn	1	Monsanto	1998	Pending

New Bio-safety Legislation

A New Bio-safety Law was adopted and approved in Ukraine in 2007.

The following is a translation of the new “Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms” that was adopted on June 21, 2007:

The "Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms" must regulate relations between executive authorities, manufacturers, suppliers, developers, researchers, scholars and consumers of genetically-modified organisms and products manufactured by technologies envisaging their development, creation, testing, study, transportation, import, export, marketing, discharge to the environment and use in Ukraine (hereinafter referred to as GMO handling) and ensuring biological and genetic safety.

Enforcement of this Law will be ensured by central executive bodies within the scope of their authority and in accordance with the procedure stipulated by law. Responsibilities of the authorities are stipulated by the law but are not distributed to the institutions (Ministry of Health, Ministry of Environment and Nature Protection, Ministry of Science and Education).

Supplementary documents must regulate the mechanism and system of:

1. Areas of activity subject to regulation in the course of GMO handling;
2. Powers of the central executive authority on agricultural policy;
3. Regulating genetic engineering activities at institutions, organizations and enterprises;
4. State registration of GMOs and establishing restrictions on their use;
5. Use, transportation, storage and recycling of GMOs.

[Comment: The newly adopted law does not establish a system or mechanisms for the creation, testing, transport and use of biotech products. The law only creates a framework for biotech products and will be followed by supplementary documents to this law that will provide the next steps and implementing regulations. The Biosafety Commission will be responsible for drafting the supplementary regulations that will govern the approval and use of GMO products in Ukraine. More specific details and a timeline are not yet available.]

Labeling

Ukraine's Current Labeling System

The Ukrainian Cabinet of Ministers adopted Decree # 985 on August 1, 2007, requiring the government of Ukraine to begin labeling biotech food products that contain GMO elements above 0.9 percent. The decree called for labeling to be in place no later then November 1, 2007. Baby food that contains biotech products cannot be imported, produced or sold in Ukraine.

After long debates in the Cabinet of Ministers over this Decree, the Cabinet of Ministers agreed to adopt Decree # 1330 on November 21, 2007, cancelling Decree # 985.

Ukrainian authorities feel they have no choice but to require labeling given their neighbors and major trading partners, the EU and Russia. They also believe they must follow the EU in using a threshold to trigger labeling of 0.9 percent "GM" content, although they acknowledge this threshold is not based on science or any critical analysis. The Ministry of Health refused to be responsible for mandatory labeling, recognizing there are no safety or public health issues that would justify it, but the State Committee on Technical Regulation and Consumer Policy believes its approach to consumer-right-to-know labels is fully consistent with the US FDA/FFDCA mandate that labels be accurate, informative, and not misleading.

Ukraine's labeling direction seems to be driven by a desire to test widely in order to affirm that any GM material found in food imported into Ukraine is registered for import and consumption, and that anything not registered would be prohibited. Ukraine plans to build 25 regional testing labs that will be distributed around the country.

The approach Ukraine is taking is acutely vulnerable to a WTO challenge because their measures clearly will produce results disproportionate to any recognized risk and without benefit of any scientific justification. However, the government continues down this path primarily to capture the revenues that are expected to be generated from such testing.

The legislation will be adopted to reflect the consumers' "right to know", especially because Ukraine does not conduct food safety risk assessments for GMOs at this point. The current labeling legislation is unclear on label language, placement or threshold. The implementing regulations entitled "On Approving Rules of Retail Trade in Food Products" adopted by the Ministry of Economy on July 23, 2003 did not clarify these issues. The regulations simply prohibited the sale of domestically produced and imported consumer packaged food products that do not have an "easy to comprehend" label.

Unofficial tests of consumer–ready products conducted by Ukrainian labs capable of identifying selected GM components revealed possible presence of GM components in some products that are readily for sale in Ukraine. So far, the domestic food industry and food importers are not labeling GM products due to the lack of clarity of the requirements. Ukrainian state agencies also chose to ignore labeling requirements due to limited lab facilities, illicit testing techniques, lack of maximum residue level threshold, as well as legislative ambiguities.

Under the current system, there are no labeling requirements applicable to biotech feeds. However, Ukraine's current GMO labeling rules represent one of the major uncertainties for food importers. Food products that contain GMOs were not regulated prior to October 24, 2002, the date when the Parliament of Ukraine incorporated changes into the Law of Ukraine On Food Safety. The legislation included food products that contain "genetically modified components" to the category of new food products along with newly developed foods, products that have not been imported before, products that contain new components/ingredients and products that were produced using new technology. A separate line on the presence of GMOs in food products was included to the list of mandatory information to be provided on the label. It appears that any quantity of GMOs must be labeled according to the Law.

Section IV. Marketing Issues

Due to frequent regulatory changes in Ukraine, U.S. exporters are reminded to check with their importers on applicable regulations and documentation requirements prior to exporting to Ukraine. Interested exporters may learn more about food and agricultural import regulations and standards by downloading the following report prepared by FAS-Kyiv http://www.fas.usda.gov/gainfiles/200508/146130466.pdf

Section V. Capacity Building and Outreach

U.S. government agencies have conducted a number of outreach activities that targeted the creation of an effective and transparent biotechnology regulatory framework. New outreach activities are also scheduled in September 2008.

In April 2008, a U.S. biotech expert traveled to Ukraine to participate in a few outreach activities and a Ukrainian government sponsored conference. This is the first time the government of Ukraine presented a balanced approach to this issue and also encouraged fruitful dialogue. The expert was also able to have important discussions with relevant media.

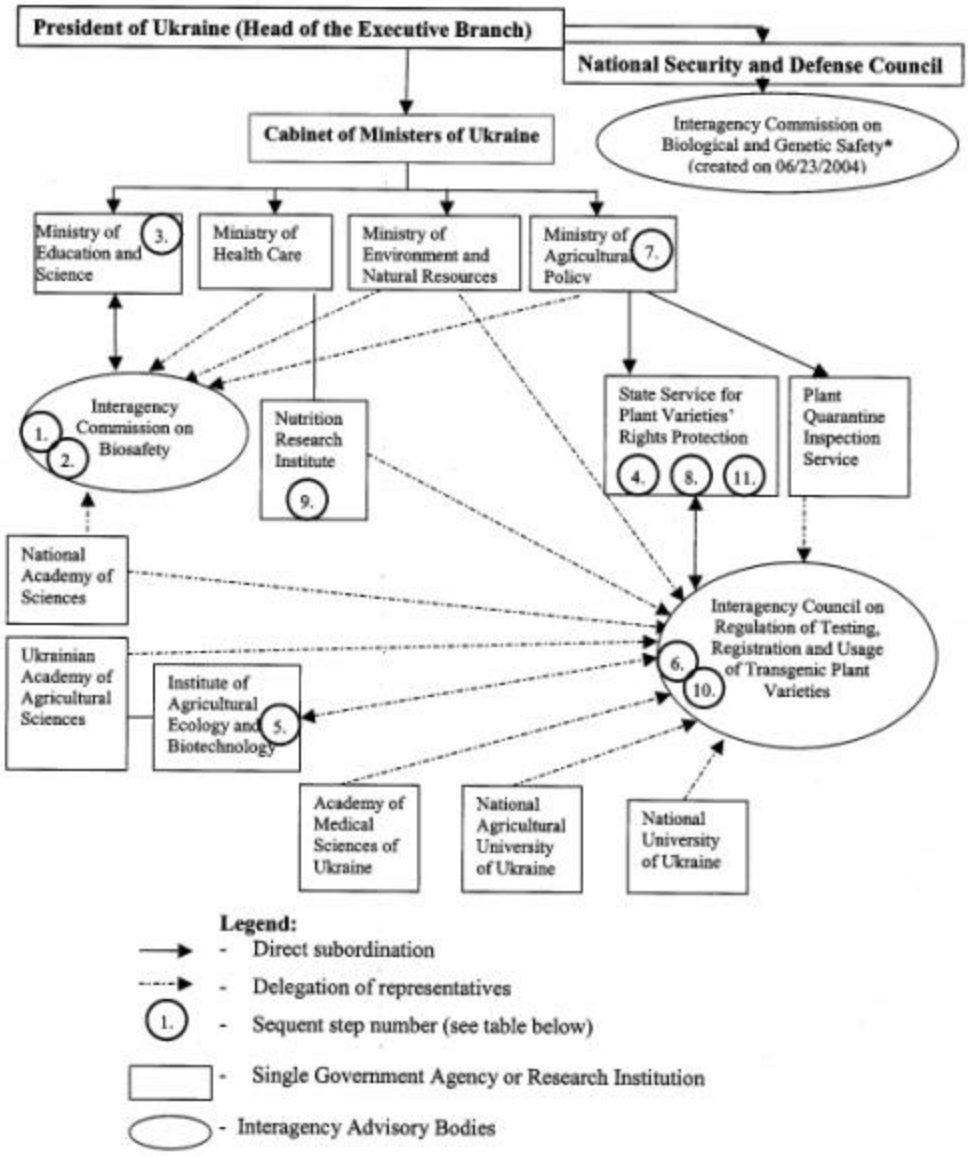
In 2006, approximately 50 scientists, graduate students and regulators from various Ukrainian research institutes and regulatory agencies representing 20 of the 25 Ukrainian oblasts were present, providing excellent regional coverage. All presentations from this seminar were posted on http://www.auapb.org/eng/pageseng/5.htm.

In 2002, four Ukrainian scientists from the State Service on Plant Variety Rights Protection of the Ministry of Agricultural Policy, Institute of Ecohygiene and Toxicology of the Ministry of Health Care, Institute of Cell Biology and Genetic Engineering of the National Academy of Sciences and the Ukrainian Academy of Agricultural Sciences participated in a two-week training program under the Cochran Fellowship Program. The program helped to educate key Ukrainian researchers on the roles played by USDA, Food and Drug Administration and Environmental Protection Agency in the U.S. coordinated biotechnology regulatory framework as well as to provide more detailed information on APHIS biotech regulations.

The Department of State invited two Ukrainian scientists, two regulators and one journalist on the program entitled "Agricultural Biotechnology for Sustainable Development" in 2000 under the International Visitors Program. This was the first opportunity in Ukraine to study the U.S. biotechnology regulatory system. The trip helped in preparing the initial draft of Ukraine's biosafety law and provided an excellent opportunity to initiate a series of well-balanced articles on agricultural biotechnology (http://www.zerkalo-nedeli.com/nn/show/419/36760/; http://www.zerkalo-nedeli.com/nn/show/317/28987/; http://www.zerkalo-nedeli.com/nn/show/372/33134/). "Dzerkalo Tyzhnya" Weekly, one of the most reputable Ukrainian newspapers published articles and also hosted an electronic round table with participation of scientists from the U.S. Agency for International Development http://www.zerkalo-nedeli.com/nn/show/317/28987/. Articles and the transcript of the round table are available in Russian.

Appendices

Appendix A. The Scheme of Ukraine's Biotechnology Regulatory Process As It Currently Applies to Biotech Crops.



Prepared by FAS-Kyiv based on available Ukrainian Regulations and interviews with industry experts.

Appendix B. Steps Necessary To Register a Biotech Crop in Ukraine

Phase	Step	*Description*	*Responsible Agency*	Required time
State Registration of the GMO.	1	Application for GMO's environmental release and registration (The GMO must meet the two following criteria: absence of hazard for human health and the environment (if used as intended); identifiability)	Interagency Commission on Biosafety (ICB) (currently under the Ministry of Science and Education of Ukraine. According to the Draft Biosafety Law, ICB will report directly to the Cabinet of Ministers of Ukraine)	
	2	The ICB conducts environmental risk assessments and issues one of three possible verdicts: a. - release of the GMOs into the environment is safe; b. - release of the GMOs into the environment is safe subject to specific requirements; c. - release of the GMO into the environment is potentially unsafe	ICB	
	3	The GMOs that received a or b-type verdicts (step #2) are to be included into the State Register of the GMOs*.	ICB, Ministry of Education and Science	**270 days**
Import Permit for Testing	4	Application to import GMP plants for variety testing	State Service for Plant Varieties Rights Protection under the Ministry of Agricultural Policy of Ukraine (SSPVRP/MAPU)	**Unknown**
	5	Application is forwarded for an examination	Institute of Agricultural Ecology and Biotechnology, Ukrainian Academy of Agricultural Sciences	**Unknown**
	6	Supporting letter is sent to the Ministry of Agricultural Policy	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	**Unknown**
	7	Import permit for testing is issued	Ministry of Agricultural Policy of Ukraine	**30**
Testing	8	Usual State Plant Variety Testing Program under control of the Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties	SSPVRP/MAPU	**2-3 years**
	9	GM samples are sent for a food safety assessment	Nutrition Research Institute under the Ministry of Health Care of Ukraine	**Unknown**
	10	Approval of the GM variety subject to favorable test results (steps 9-10)	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	**Unknown**
Final permit	11	Entry of the GM plant variety into the State Register of Plant Varieties of Ukraine Note: Although, GM plant variety testing is to be conducted the same way as for conventional varieties, GM varieties have to be included into a separate section of the State Plant Varieties Register	SSPVRP/MAPU	**Unknown**
Estimated minimum time required				**3-4 years**

* Presidential Degree established Interagency Commission on Biological and Genetic Safety under the National Security Council of Ukraine on 06/23/2004. It is yet another advisory body responsible for biosafety issues. It is expected, however, that this Commission will pay more attention to bioterrorism-related problems.

Appendix C. Agency Responsibilities As Prescribed by the New Ukrainian "Law of the State System of Biosafety for Creating, Testing, Transporting and Usage of Genetically Modified Organisms" (not yet implemented).

The Cabinet of Ministers of Ukraine must:

- ensure state regulation and control in the area of GMO handling and genetic engineering activities;
- ensure measures regarding state support of genetic engineering activities;
- direct and coordinate the work of central executive authorities and other executive bodies in the area of GMO handling and genetic engineering activities;
- organize international cooperation to ensure safe GMO handling and the development of scientific knowledge in this field;
- approve the procedures for the state registration of GMOs and products manufactured using GMOs;
- approve the procedures for importation of GMO sources of food products and feed manufactured from GMOs;
- approve the procedure for granting a permit for the transit of GMOs across the territory of Ukraine;
- approve the procedure for licensing genetic engineering activities in closed and open systems;
- approve the procedure for conducting state approbation (tests) of GMOs in the open system and obtaining a permit for conducting those;
- approve the safety criteria for GMO handling in closed systems.

Central Executive Authority on Education and Science must:

- ensure the development of scientific and scientific-and-technical potential in the field of genetic engineering activities;
- ensure protection of international and national patents and other types of intellectual property in the field of GMO handling, genetic engineering and genetic engineering activities;
- develop the safety criteria for GMO handling and the genetic engineering activity in closed systems;
- develop and improve the system of control over the observance of safety rules in genetic engineering activities;
- carry out licensing of genetic engineering activities in closed systems;
- issue permits for importation of unregistered GMOs, if they are used exclusively for science research purposes in closed systems and open systems and also for the purpose of state testing, with regard to the results of the state ecological and state sanitary and epidemiological inspections regarding the biological and genetic safety of GMOs that are carried out based on recognized international approaches,.

Central Executive Authority on Ecology and Natural Resources must:

- conduct state ecological inspections of GMOs intended for use in open systems;
- develop criteria which is based on scientific principles and international experience for assessing risk of the potential GMO impact on the natural environment;
- carry out state registration of plant protection **means manufactured using GMOs**;
- exercise state supervision and control over the observance of biological and genetic safety measures in respect to biological objects in the natural environment for creating, studying and practical use of GMOs in open systems;
- issue permits to discharge GMOs in open systems.

Central Executive Authority on Health Protection must:

- develop the criteria which is based on scientific principles and international experience for assessing the risk of GMOs and the potential impact on human health and products manufactured using GMOs, including food products;
- carry out state sanitary and epidemiological inspections of GMOs that are used in open systems to determine their biological and genetic safety for humans and with the view towards gaining state registration;
- carry out state supervision and control over observance of biological and genetic safety measures with respect to humans in creating, studying and practical use of GMOs in open systems;
- carry out state sanitary and epidemiological inspections of products manufactured using GMOs to determine their safety for human health and life;
- carry out state registration of GMO sources of food products as well as state registration of food products, cosmetics, and medicines containing GMOs or manufactured using GMOs;
approve the list of food products, which contain GMO content and the list of relevant methodologies for detecting and identifying GMOs;
- monitor food products manufactured using GMOs to ensure only registered GMO sources are used.

Central Executive Authority on Agricultural Policy must:

- ensure state approbation (testing) and state registration of agricultural plant varieties, animal breeds, microbiological agricultural and veterinarian preparations created based on GMOs;
- carry out state supervision and control over biological and genetic safety measures with respect to agricultural plants and animals in creating, studying and practical use of GMOs in open systems at companies, institutions and organizations of agricultural and industrial complexes irrespective of their subordination and ownership;
- carry out state registration of GMO sources of feed as well as registration of feed additives and veterinarian preparations containing GMOs or manufactured with the use thereof;
- approve the list of feed in which control over the content of GMOs is carried out as well as the list of relevant methodologies for detecting and identifying GMOs;
- monitor feed manufactured using GMOs to ensure only registered GMO sources are used.